

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

FILED
Jan 11, 2025, 10:55 PM
in the Clerk's Office
U.S. District Court,
EDNY, Brooklyn
Pro Se Office via
Box.com

UNITED STATE OF AMERICA
PLAINTIFF

§

v.

Case No. 22-CV-1159
January 11, 2025.

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ANDREW SINCLAIR / B4B EARTH TEA
LLC

DEFENDANT

Paragraph 3 Rebuttal Response: Clarifying the Study Findings on Compound Absorption and Immune Recognition.

The study conducted on B4B Earth Tea Immune Support Drink provides robust scientific evidence clearly supporting its efficacy in immune system modulation. Below are key points addressing concerns and reinforcing the validity of the findings:

1. Absorption of Bioactive Compounds

The compounds in B4B Earth Tea Immune Support Drink exhibit clear bioavailability, demonstrated through significant modulation of cytokine levels—key immune signaling molecules indicating systemic absorption. Specifically:

- Pro-inflammatory and anti-inflammatory cytokines (e.g., IL-6, IL-10, TNF-alpha) showed notable changes post-consumption, clearly

supporting the absorption of the bioactive compounds and their active influence on immune pathways.

- Array data corroborates that these compounds are not only absorbed but are also bioactive, triggering immune responses at the cellular level.

2. Immune System Recognition

The immune system's response to B4B Earth Tea Immune Support Drink is clearly supported by measurable markers of immune recognition, including:

- Elevated levels of interferon-gamma (IFN-gamma), a critical mediator for immune surveillance, indicating enhanced detection and activation of immune responses.
- Modulation of MCP-1, a key molecule involved in immune cell recruitment, further validating that the immune system identifies and interacts with the bioactive compounds in the drink.

3. Methodological Rigor

The study employed a multiplex sandwich ELISA, a well-established technique that ensures the accuracy and sensitivity of cytokine quantification, strengthening the reliability of the results:

- Replicability: Each cytokine was assessed in quadruplicate to ensure reproducibility and minimize variability.
- Validation: The use of standard curves and controls confirms the validity of the cytokine data, clearly supporting the conclusion that B4B Earth Tea Immune Support Drink compounds effectively engage with immune pathways.

4. Broader Implications

The ability of B4B Earth Tea Immune Support Drink to modulate both pro-inflammatory and anti-inflammatory markers highlights its potential for promoting immune system balance, crucial for maintaining homeostasis—especially during stress or disease. The drink's dual action provides a therapeutic edge in supporting the immune system in diverse conditions.

5. Product Sample Details

The product samples used in the study are clearly outlined in the raw data and match the study parameters from the previously submitted ELISA study. Specific sample information is as follows:

Sample #	Sample ID	Sample Type	Sample Conditions	Dilution
1	BETISD 1	Drink	4°C; Unfiltered 1	2x
2	BETISD 2	Drink	4°C; Unfiltered 2	2x
3	BETISD 3	Drink	4°C; Filtered 1	2x
4	BETISD 4	Drink	4°C; Filtered 2	2x
5	BETISD 5	Drink	Room Temperature; Unfiltered 1	2x
6	BETISD 6	Drink	Room Temperature; Unfiltered 2	2x
7	BETISD 7	Drink	Room Temperature; Filtered 1	2x
8	BETISD 8	Drink	Room Temperature; Filtered 2	2x

6. Conclusion

The study provides compelling evidence that B4B Earth Tea Immune Support Drink's bioactive compounds are absorbed and recognized by the immune system, with measurable changes in cytokine activity confirming the product's efficacy in immune modulation.

Any rebuttal of these findings disregards the scientific rigor of the study and the direct immune biomarkers demonstrated. Furthermore, this explanation reinforces why the definition of a “drug” specifically excludes food. All foods contain bioactive compounds that affect the human body in various ways. To label B4B Earth Tea Immune Support Drink as a drug would imply that all plants, which naturally contain compounds influencing bodily functions, would also be considered drugs. This would not only contradict the current understanding of food and drug classification but would also lead to an unnecessarily broad categorization that undermines the role of food in maintaining health.

Respectfully submitted,

/s/ Andrew Sinclair

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Defendant

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